K080167

510(k) Summary

AUG - 8 2008

Submitter information

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Date summary prepared: July 10, 2008

Device Trade or Proprietary Names: ADVIA Centaur FT4 Immunoassay

Device Common/Usual Name or Classification Name: Free Thyroxine test system

Classification Number / Class: 21CFR 862.1695 / Class II

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: k080167

Assay Predicate Device:

	Predicate Device
Device Name	ACS:180 Free T4 Assay
Common name	ACS FrT4
510(k) Number	k961510
Manufacturer	Siemens Healthcare Diagnostics (formerly Siemens Medical Solutions Diagnostics)

Device Description:

The ADVIA Centaur FT4 assay is a competitive immunoassay using direct, chemiluminescent technology. Free thyroxine in the patient sample competes with acridinium ester-labeled T4 in the Lite Reagent for a limited amount of biotinylated polyclonal rabbit anti-T4 antibody that is bound to avidin that is covalently coupled to

paramagnetic particles in the Solid Phase. There is an inverse relationship between the concentration of free thyroxine in the sample and relative light units (chemiluminescence).

Statements of Intended Use:

The ADVIA Centaur FT4 Immunoassay is for *in vitro* diagnostic use in the quantitative determination of free thyroxine (FT4) in serum or plasma (heparinized or EDTA) using the ADVIA Centaur and ADVIA Centaur XP Systems. Measurements of free thyroxine are used in the diagnosis and treatment of thyroid diseases.

Comparisons to the Predicate Device:

Assay Similarities

	ADVIA Centaur FT4 Assay ***(new device)***	**ACS:180 FrT4 Assay** ***(predicate device)***
Intended Use	For *in vitro* diagnostic use in the quantitative determination of free thyroxine (FT4) in serum or plasma	For *in vitro* diagnostic use in the quantitative determination of free thyroxine (FT4) in serum
Assay Method	Competitive immunoassay	Competitive immunoassay
Detection	Chemiluminescence	Chemiluminescence
Assay Range	0.1 – 12.0 ng/dL	0.1 – 12.0 ng/dL
Calibrators	Calibrator A	Calibrator A
Calibration	2 point	2 point
Reagents	Two liquid reagents, ready to use	Two liquid reagents, ready to use
Lite Reagent	Acridium ester labeled T4	Acridium ester labeled T4
Expected Values (ng/dL)	Euthyroid 0.89 – 1.76 Hypothyroid < 0.89 Hyperthyroid >1.76	Euthyroid 0.89 – 1.76 Hypothyroid < 0.89 Hyperthyroid >1.76
Standardization	Internal Standard (USP)	Internal Standard (USP)

Assay Differences

	ADVIA Centaur FT4 Assay ***(new device)***	**ACS:180 FrT4 Assay** ***(predicate device)***
Specimen Type	Human serum or plasma (heparinized or EDTA)	Human serum
Solid Phase Reagent	Biotin-labeled polyclonal anti-T4 bound to avidin paramagnetic particles	Polyclonal anti-T4 bound to paramagnetic particles

Performance:

Substantial equivalence was demonstrated by testing several method performance characteristics including imprecision, method comparison, interfering substances, and specificity. The following tables summarize the precision (total), interfering substances, specificity, serum / plasma equivalency and method comparison results.

All of the evaluation studies gave acceptable results compared to the predicate device. These studies support that the ADVIA Centaur FT4 immunoassay is substantially equivalent to the ACS:180 FrT4 immunoassay that is currently marketed.

Imprecision

ADVIA Centaur FT4		ACS:180 FrT4	
Level (ng/dL)	Total CV (%)	Level (ng/dL)	Total CV (%)
0.37	11.2	0.58	4.86
0.71	4.85	--	--
1.31	3.98	1.42	1.92
3.35	4.07	3.37	3.55
5.32	4.02	--	--
9.68	6.53	--	--

ADVIA Centaur FT4	
Level (ng/dL)	Total CV (%)
0.72	4.16
1.47	4.58
3.01	4.44

Study #2 - Multiple reagent lots, multiple systems

Specificity

The cross-reactivity of the ADVIA Centaur FT4 assay with a substance can be expressed as the ratio of:

- the amount of T4 required to displace 50% of the maximally bound labeled T4 from the anti-T4 antibody,
- the amount of the cross-reactant to give the same 50% displacement

Cross Reactant	% Cross Reactivity
L-Triiodothyronine	<0.02%
Diiodotyrosine	<0.02%
Monoiodotyrosine	<0.02%
3,5-Diiodo-L-thyronine	<0.02%
Reverse Triiodothyronine (rT3)	<0.02%

Interfering Substances

Interfering Substance	Interferent Conc. (mg/dL)	FT4 conc. (ng/dL)	Effect (% change)
Hemoglobin	300	0.90	-1.10
Hemoglobin	300	1.34	-4.29
Lipids (Intralipids)	1000	1.10	3.77
Lipids (Intralipids)	1000	1.37	5.38
Bilirubin, free	20	1.03	3.00
Bilirubin, free	20	1.23	2.50
Bilirubin, conjugated	20	1.03	5.10
Bilirubin, conjugated	20	1.23	2.50

Correlation

(y = ADVIA Centaur FT4, x = comparison method/system)

Specimen type, System (y)	Comparison System (x)	N	Regression Equation	r	Sample Range (ng/dL)
Serum, ADVIA Centaur FT4	Serum, ACS:180 FrT4	283	Y = 0.973 x + 0.016	0.995	0.14 – 11.1

Serum / Plasma (Lithium heparin and EDTA)

Specimen type (y)	Comparison System (x)	N	Regression Equation	r	Sample Range (ng/dL)
Heparinized Plasma	Serum	133	Y = 0.979x + 0.058	0.997	0.17 – 11.4
EDTA Plasma	Serum	108	Y = 0.967x + 0.007	0.998	0.17 – 11.4

Conclusions:

The Siemens Healthcare Diagnostics ADVIA Centaur FT4 immunoassay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Siemens Healthcare Diagnostics ACS:180 FrT4 immunoassay (k961510).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics
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Re: k080167
Trade Name: ADVIA Centaur FT4 Immunoassay
Regulation Number: 21 CFR 862.1695
Regulation Name: Free thyroxine test system
Regulatory Class: Class II
Product Codes: CEC
Dated: June 16, 2008
Received: June 17, 2008

Dear Dr. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known): k080167

Device Name: ADVIA Centaur FT4 Immunoassay

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Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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